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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1666]

Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the patent and exclusivity notification requirements under the new drug application (NDA) and abbreviated new drug application (ANDA) regulations.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions (OMB Control Number 0910–0305)—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) requires patent owners to submit to FDA information about patents that cover approved drugs. Generic copies of these drugs may be approved when the patents expire or if a generic company certifies that the patent is invalid or will not be infringed. In such cases, the generic company must notify the patent owner about the certification, and approval of the drug may not be made effective until after the court decides the patent infringement suit or a period of 36 months, whichever occurs

first. In addition, section 505 of the act provides several periods of marketing exclusivity ranging from 3 to 10 years (depending primarily on the nature of the innovation). If a drug product receives marketing exclusivity, FDA will not approve (or, in limited cases not receive) an ANDA for the drug product.

Under the authority found in sections 505 and 701 of the act (21 U.S.C. 371), FDA issued regulations governing patent and exclusivity provisions in 21 CFR part 314. The regulations provide instructions for NDA applicants (including section 505(b)(2) of the act applicants) and ANDA applicants on how to file patent information and request marketing exclusivity; require patent certification information for section 505(b)(2) applications and ANDA's; require information for requests for marketing exclusivity for NDA's (including section 505(b)(2) applications and certain NDA supplements); and require patent information for NDA's.

The specific reporting requirements that are the subject of this information collection are as follows:

21 CFR 314.50(i)—Requires the submission of patent certification information.

21 CFR 314.50(j)—Requires the submission of marketing exclusivity information.

21 CFR 314.52—Requires notice of certification of invalidity or noninfringement of a patent.

21 CFR 314.53—Requires the submission of patent information.

21 CFR 314.54(a)(1)(vii)—Requires the submission of marketing exclusivity information.

21 CFR 314.70(e)—Requires the submission of patent information.

21 CFR 314.70(f)—Requires the submission of marketing exclusivity information.

21 CFR 314.94(a)(12)—Requires the submission of patent certification information.

21 CFR 314.95—Requires notice of certification of invalidity or noninfringement of a patent.

21 CFR 314.107(c)(4), (e)(2)(iv), and (f)—Requires notice of the date of commercial marketing; a copy of the entry of the order or judgement; notice of the filing of legal action after notice of certification.

Applicants must provide information on patents to FDA to enable the agency to determine whether a product is covered by a patent or whether approval of a proposed drug product would result in patent infringement. The agency lists the patent information as a reference of potential applicants. If an applicant believes a patent is invalid or would not be infringed, Federal law also requires it to notify the patent holder. FDA approval, in such cases, is affected should there be any patent litigation. Failure to provide this information would result in an incomplete application and constitute grounds for refusing to approve the application.

Applicants submitting NDA's are required under the act to provide information on certain patents that cover their drug products. The agency lists this patent information in its publication entitled *List of Approved Drug Products With Therapeutic Equivalence Evaluations.*

To promote product innovation, the act also gives NDA applicants several periods of ''market exclusivity'' ranging from 3 to 10 years (depending primarily on the nature of the innovation). If a drug product receives marketing exclusivity, FDA will not approve (or, in limited cases, even receive) an ANDA for the drug product during that time period.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Number fo Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
PATENT INFORMATION 314.50(h) 314.53 314.70(e)	85	3.8	325	2	650
PATENT CERTIFICATION INFORMATION 314.50(i) 314.94(a)(12)	97	3.4	331	2	662
NOTICE OF CERTIFICATION OF INVALIDITY OR NON-INFRINGEMENT OF A PATENT 314.52 314.95	37	2	75	16	1,200
MARKETING EXCLUSIVITY INFORMATION 314.50(j) 314.54(a)(1)(vii) 314.70(f)	92	2.7	250	2	500
NOTIFICATION OF DATE OF COMMERCIAL MARKETING; ENTRY OF THE ORDER OR JUDGEMENT; FILING OF LEGAL ACTION 314.107(c)(4),(e)(2)(iv),(f)(2), and (f)(3)	34	2	71	1	71
TOTAL					3,083

[1]There are no capital costs or operating and maintenance costs associated with this collection.

Dated: December 26, 2000

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Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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